UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,551	08/26/1999	TAKUYA TAMATANI	06501/039001	6738

7590 10/31/2002

JANIS K FRASER PH D J D
FISH & RICHARDSON PC
225 FRANKLIN STREET
BOSTON, MA 021102804

EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	34

DATE MAILED: 10/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/383,551	Applicant(s) TAMATANI ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2002 and 18 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-214* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *55-72 and 90-99* is/are allowed.

6)☒ Claim(s) *37-54,73-89 and 100-214* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *26, 30,* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *31* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendments, filed 7/17/02 and 10/18/02 (Paper Nos. 27 and 33), are acknowledged.
Claims 1-36 have been cancelled.
Claims 37-214 have been added.
Claims 45, 55-72, 79 and 90-99 have been amended.
Claims 37-214 are pending and are under consideration in the instant application.

2. Applicant's IDSs, filed 7/15/02, 8/22/02 and 9/30/02 (Paper Nos. 26, 30 and 32), are acknowledged.

3. Substitute drawings were received on August 19, 2002. These drawings are acceptable.

4. Priority: Acknowledgment is again made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant's communication, filed 4/19/02, regarding the filing of verified translations of priority documents PCT/JP98/00837, filed February 27, 1998; and Japanese Patent Application Nos 9/62290, filed February 27, 1997 and 10/62217, filed February 26, 1998 is acknowledged.

The verified translation of priority document PCT/JP98/00837 appears to provide adequate written support for the instant claims. In particular it is noted that adequate written support for many of the instant limitations is found on pages 44-54 of the verified translation. Support for the explicit exclusion in the claims of a "non-hamster antibody" is found on page 45, e.g., lines 15-20, in view of the alternative elements positively recited in the specification. In re Johnson, 194 USPQ 187, 196 (CCPA 1977). Support for the limitation "inhibits the activation of lymphocytes" is found on page 89 at lines 20-30, particularly in view of the usage of the phrase "regulating" in various locations to encompass inhibition (e.g., page 90 at lines 17), and further in view of the experiments indicating that the instant polypeptides expressed as cell surface molecules function to induce immune responses such as lymphocyte activation (see pages 78-81, e.g., page 78 at lines 2-35) and that "regulation" of the instant polypeptide function by blocking agents is an "inhibitory" effect (e.g. page 80 at lines 19-23 and page 81 at lines 28-32). Methods of treating glomerulonephritis are supported on pages 80-81 (Example 15).

Therefore, the filing date of the instant claims appears to be AT LEAST that of priority document PCT/JP98/00837, i.e., February 27, 1998. The Examiner has not evaluated the remaining foreign priority documents for support.

5. In view of the support provided at least in PCT/JP98/00837, which was filed February 27, 1998, Hutloff et al. (Nature January 1999, 397:263-266, of record) does not constitute prior art.

6. Applicant's cancellation of claims 27-34 has obviated the previous objections and rejections with respect to these claims.

It is noted that the C398.4A monoclonal antibody to the mouse polypeptide H4 of Redoglia et al. (Eur. J. Immunol. November 1996; 26:2781-2789, IDS #AD) is a hamster antibody. It is further noted that since the ability of C398.4A to bind human ICOS (the polypeptide of SEQ ID NO:2) was not appreciated until after the time the instant invention was made, the ordinary artisan would not have been motivated to prepare alternate forms of the C398.4A antibody (i.e., chimeric, humanized, human).

7. Applicant's cancellation of claims 27-34 in copending Application No. 09/561,308 has obviated the provisional rejection under 35 U.S.C. 101.

8. The following New Grounds of Rejection are set forth herein.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 37-54, 73-89 and 100-214 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 10-15, 18-22 and 25-30 of copending Application No. 09/830,548 as evidenced by the sequence listing of WO98/38216. Although the conflicting claims are not identical, they are not patentably distinct.

The instant claims are drawn to antibodies in various forms to polypeptides identified by individual SEQ ID NOS that are human, rat and mouse JTT antigen polypeptides.

Claims 7, 15, 22 and 30 of copending Application No. 09/830,548 recite "antibodies which bind AILIM" as pharmaceutical compositions which have intended uses in various methods that involve modulation of signal transduction mediated by AILIM (claims 1-6, 10-14, 18-21 and 25-29). Although the claims 1, 10, 18 and 22 recite pharmaceutical compositions generically, antibodies to AILIM and pharmaceutical compositions comprising are obvious embodiments of the generic claims, in view of the recitation of antibodies in claims 7, 15, 22 and 30.

Copending Application No. 09/830,548 does not recite antibodies to particular SEQ ID NOS, nor does it recite antibodies in the various forms recited in the instant claims or the cells producing said antibodies.

However, copending Application No. 09/830,548 defines "AILIM" on page 17 at lines 13-30 to mean human AILIM/JTT-1 antigen of SEQ ID NO:1; rat AILIM/JTT-1 antigen of SEQ ID NO:4 or 6; and mouse AILIM/JTT-1 antigen of WO98/38216. The amino acid sequences set forth as encoded by the cDNAs of SEQ ID NO:1, 4, 5 and 6 of WO98/38216 are the same as instant SEQ ID NOS:2, 13, 14 and 15, respectively, as evidenced by the Sequence Listing of WO98/38216.

Therefore, although antibodies to the polypeptides of the instant SEQ ID NOS are not explicitly recited in the claims of copending Application No. 09/830,548; they nevertheless are obvious embodiments of the recited invention. In view of claims 1-7, 10-15, 18-22 and 25-30 of copending Application No. 09/830,548, as evidenced by WO98/38216, an antibody to an AILIM polypeptide is an antibody to the polypeptide of any one of SEQ ID NOS:2, 13, 14, or 15. It is noted that even were only one of the SEQ ID NOS used as an immunogen, an antibody produced by immunizing with, e.g., SEQ ID NO:2 would also bind the rat and mouse polypeptides due to numerous conserved epitopes among the polypeptides.

In addition, the ordinary artisan would have found it obvious to produce antibodies in any of a variety of art-recognized forms. The ordinary artisan would have been motivated to produce chimeric, humanized, or human antibodies in particular, because pharmaceutical compositions for use in humans optimally employ antibodies in these forms. In view of the definition of AILIM in copending Application No. 09/830,548 as evidenced by WO98/38216, the ordinary artisan would have been motivated to produce antibodies to these particular SEQ ID NOS because they represent the known AILIM polypeptides and antibodies to the polypeptides of different species are applicable in disease model systems for evaluating pharmaceutical compositions comprising antibodies to AILIM. In the absence of guidance to production of only hamster antibodies, the antibodies of copending Application No. 09/830,548 necessarily include non-hamster antibodies, e.g., a human antibody. Further, the ordinary artisan would have been motivated to select antibodies which bind the extracellular domain of the polypeptide because AILIM is a cell surface protein.

Finally, isolated cells producing the antibodies and methods of making said antibodies, although also not recited in copending Application No. 09/830,548, are nevertheless obvious in view of claims reciting the antibodies and a teaching of an isolated polypeptide bound by the antibody, since methods of making antibodies of a desired specificity in any of a variety of forms were well known in the art at the time the invention was made. The ordinary artisan would have been motivated to use methods of making antibodies comprising the instant steps in order to produce cells that produce the recited antibody in unlimited supply.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Applicant is advised that should the claims of copending Application No. 09/830,548 be re-written as method claims, a similar rejection with respect to pending claims 55-72 and 90-99 would appear to be appropriate.

12. Claims 37-54, 73-89 and 100-214 are directed to an invention not patentably distinct from claims 1-7, 10-15, 18-22 and 25-30 of commonly assigned Application No. 09/830,548 for the reasons set forth supra.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned Application No. 09/830,548, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

13. Claims 37-38, 40-42, 45-47, 49-51, 54, 73-76, 79-81, 84-86, 89, 100-101, 104-108, 110-113, 115-116, 118-120, 123-125, 127-129, 132-136, 139-141, 144-146, 149-151, 154-158, 160-163, 165-166, 168-170, 173-175, 177-179, 182-186, 189-191, 194-196, 199-201, 204-208, 210-213 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-100 of copending Application No. 09/859,053 as evidenced by the sequence listing of WO98/38216. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are drawn to antibodies in various forms to polypeptides identified by individual SEQ ID NOS that are human, rat and mouse JTT antigen polypeptides, as well as to cells producing said antibodies and pharmaceutical compositions comprising.

Claims 1-100 of copending Application No. 09/859,053 recite in various forms human antibodies which bind an AILIM polypeptide, DNA encoding such antibodies, and cells producing such antibodies. The claims of copending Application No. 09/859,053 recite both the genus of human antibodies to an AILIM polypeptide, and species that are particular human antibodies of AILIM (including the DNA encoding and cells producing).

Copending Application No. 09/859,053 does not recite antibodies to particular SEQ ID NOS, nor does it recite antibodies in the various forms recited in the instant claims.

However, copending Application No. 09/859,053 defines "AILIM" page 59 line 30 to page 60 line 7 to mean the human, rat, rat variant or mouse polypeptides found in WO98/38216. The human AILIM/JTT-1 antigen encoded by SEQ ID NO:1; rat AILIM/JTT-1 antigen encoded by SEQ ID NO:4 or 6; and mouse AILIM/JTT-1 antigen encoded by SEQ ID NO:5 of WO98/38216 are the same as instant SEQ ID NOS:2, 13, 14 and 15, respectively, as evidenced by the Sequence Listing of WO98/38216.

Therefore, although antibodies to the polypeptides of the instant SEQ ID NOS are not explicitly recited in the claims of copending Application No. 09/859,053; they nevertheless were obvious embodiments of the recited invention. The ordinary artisan would clearly have been motivated to produce human antibodies to at least the polypeptide of instant SEQ ID NO:2 (human AILIM) in order to have a reagent that could be used in methods of treating humans. In addition, any human antibody produced to the human AILIM polypeptide of SEQ ID NO:2 would also bind the rat and mouse AILIM molecules of instant SEQ ID NOS:13-15 because of the numerous shared epitopes between SEQ ID NO:2 and the mouse and rat sequences. Further, the species of human antibodies to human AILIM recited in the claims of copending application 09/859,053 anticipate claims to non-hamster antibodies to the various polypeptides, since a human antibody is a non-hamster antibody. Claims reciting DNA encoding and cells producing such antibodies also render obvious the human antibodies they encode or produced, since the purpose of the DNA and cells is to produce the human antibody. Finally, methods of making human antibodies as recited were well known in the art at the time the invention was made, and obvious in view of any teaching to make human antibodies using particular polypeptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 37-38, 40-42, 45-47, 49-51, 54, 73-76, 79-81, 84-86, 89, 100-101, 104-108, 110-113, 115-116, 118-120, 123-125, 127-129, 132-136, 139-141, 144-146, 149-151, 154-158, 160-163, 165-166, 168-170, 173-175, 177-179, 182-186, 189-191, 194-196, 199-201, 204-208, 210-213 are directed to an invention not patentably distinct from claims 1-100 of commonly assigned Application No. 09/859,053 for the reasons set forth supra.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned Application No. 09/859,053, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

15. Claims 55-72 and 90-99 appear to be allowable.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
October 23, 2002

Phillip Gambel
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
10/24/02